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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,485

Applicant(s)

MIRA ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 11-19, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 11-19, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 11-19, 23 and 24 are pending.

Applicant's amendment filed September 27, 2004 is acknowledged, and applicants' response has been fully considered. Claims 1-4 and 11-19 have been amended, claims 5-10 and 20-22 have been cancelled, and a new claim 24 has been added. Therefore, claims 1-4, 11-19, 23 and 24 are examined.

Oath/Declaration

2. A new oath or declaration filed September 27, 2004 is acknowledged.

Objection Withdrawn

3. The previous objection of claims 1-5, 11-19 and 23 is withdrawn in view of applicant's amendment to the claim and applicant's response at page 6 in the amendment filed September 27, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 101

4. The previous rejection of claims 1-5, 11 and 12 under 35 U. S. C. 101, is withdrawn in view of applicant's amendment to the claim, and applicant's response at pages 6-7 in the amendment filed September 27, 2004.

Claim Rejections - 35 USC § 112

5. The previous rejection of claim 5 under 35 U. S. C. 112, first paragraph, is withdrawn in view of applicant's cancellation of the claim in the amendment filed September 27, 2004.

Claim Objections

6. Claim 24 is objected to because of the use of “SEQ.ID.NO.SEQ ID NO: 2” or “SEQ.ID.NO.SEQ ID NO:3”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 11-19, 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4, 11-19, 23 and 24 are directed to a peptide having an amino acid sequence of SEQ ID NO:2 or 3; a mixture of peptides comprising at least a peptide having an amino acid sequence of SEQ ID NO:2 or 3, and at least a peptide having an amino acid sequence consisting of 3 to 30 contiguous amino acids of SEQ ID NO: 4; a cosmetic or pharmaceutical composition comprising the peptide or peptide mixture; and a method of reducing or eliminating wrinkles or facial asymmetry by applying the cosmetic composition. While the specification indicates that the invention provides a peptide that has a sequence made up of 3 to 30 adjacent amino acids contained on the amino end of protein SNAP-25, which inhibits neuronal exocytosis; and a mixture of at least one of the N-terminal peptides of SNAP-25 and at least one peptide that has a sequence made up of 3 to 30 adjacent amino acids contained on the carboxyl end of protein

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SNAP-25 (page 3), the specification does not disclose a genus of variants for a peptide having (comprising) an amino acid sequence of SEQ ID NO:2 or 3, where the amino acid residue is D- or L-amino acid; a mixture of peptides comprising at least a peptide having an amino acid sequence of SEQ ID NO:2 or 3, and at least a peptide having an amino acid sequence consisting of 3 to 30 contiguous amino acids of SEQ ID NO: 4; a cosmetic or pharmaceutical composition comprising the peptide or peptide mixture; and a method of reducing or eliminating wrinkles or facial asymmetry by applying the cosmetic composition.

The specification discloses the peptides of SEQ ID NO:2, 3, 5 and 6 have been synthesized; the peptide of N-terminal fragment of SNAP-25 (SEQ ID NO:2 and 3), the peptide of C-terminal fragment of SNAP-25 (SEQ ID NO:5 and 6), or a mixture of SEQ ID NO:2 or 3 and SEQ ID NO:5 or 6, which inhibits catecholamine exocytosis; and the peptides decrease the formation or stability of SNAR protein complex (Example 1). However, the specification does not describe a genus of variants for a peptide having an amino acid sequence of SEQ ID NO:2 or 3, where the amino acid residue is D- or L-amino acid; a mixture of peptides comprising at least a peptide having an amino acid sequence of SEQ ID NO:2 or 3, and at least a peptide having an amino acid sequence consisting of 3 to 30 contiguous amino acids of SEQ ID NO: 4; a cosmetic or pharmaceutical composition comprising an effective amount of the peptide or peptide mixture to reduce or eliminate wrinkles or facial asymmetry. A description of a specific N-terminal fragment of SNAP-25 (SEQ ID NO:2 or 3), C-terminal fragment of SNAP-25 (SEQ ID NO:5 or 6), or a mixture of the N-terminal fragment and C-terminal fragment of SNAP-25 does not provide original descriptive support for a peptide having an amino acid sequence of SEQ ID NO:2 or 3; a mixture of peptides comprising at least a peptide having an amino acid sequence of

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SEQ ID NO:2 or 3, and at least a peptide having an amino acid sequence consisting of 3 to 30 contiguous amino acids of SEQ ID NO: 4. The disclosure of these specific N-terminal and C-terminal fragments of SNAP-25 does not meet the written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116.)

The skilled artisan cannot envision all the contemplated peptides or peptide mixtures for a peptide having an amino acid sequence of SEQ ID NO:2 or 3, or a mixture of peptides comprising at least a peptide having an amino acid sequence of SEQ ID NO:2 or 3, and at least a peptide having an amino acid sequence consisting of 3 to 30 contiguous amino acids of SEQ ID NO: 4 based upon the general suggestion of specific N-terminal and C-terminal peptides of SNAP-25, where the functions of the peptides or peptide mixtures are not defined. The detailed sequences of peptide or peptide mixtures must be taught, therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of preparation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30

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USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF'S were found unpatentable due to lack of written description for the broad class.

Therefore, only those embodiments described and disclosed meet the written description requirement and not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2, 13-19, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 2 recites the limitation "L-amino residues" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding "D-amino acid", applicants indicate claim 1 is not limited to a specific stereoisomer, accordingly, claim 2 is definite. Applicants' response has been considered and found persuasive, thus, the previous rejection is withdrawn. The amino acid sequence of SEQ ID NO:2 or 3 in the Sequence Listing only contains L-amino acids, however, since claim 1 recites a synthetic peptide "having" an amino acid sequence of SEQ ID NO:2 or 3, and the term "having"

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reads as “comprising”, thus, the amino acid residues besides SEQ ID NO:2 or 3 in the peptide can be either L- or D-amino acid residue.

10. Claims 13-14 are indefinite because the claim recites a cosmetically effective amount of a peptide in the cosmetic composition without indicating what the effective amount of the peptide would do? Claim 14 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

11. Claims 16-19 and 23 are indefinite because the claim recites a therapeutically effective amount of a peptide in the pharmaceutical composition without indicating what the effective amount of the peptide would do? Claim 17-19 and 23 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

12. Claims 15 and 24 are indefinite because the claim lacks an essential step in the method of reducing or eliminating face wrinkles or facial asymmetry. The missing step is the outcome of the treatment.

In response, applicants indicate claim 15 has been amended and was inherent to recite the outcome of reducing or eliminating with regard to the facial wrinkle treated (page 7 of the response). Applicant's response has been considered, however, the argument is not found persuasive because the claim does not recite the end point of the process, which is to reduce or eliminate facial wrinkles or asymmetry. The term “and/or” has been deleted in the claim, thus the rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 2 remain rejected under 35 U.S.C. 102(b) as being anticipated by Montal *et al.* (WO 97/34620).

Montal *et al.* teach the amino acid sequence of SNAP-25 (Fig. 3, SEQ ID NO:1 of the WO document), which contains SEQ ID NO:2 or 3 (claim 1 and 2). The claims are anticipated by the reference because claim 1 cites a peptide “having” an amino acid sequence of SEQ ID NO:2 or 3, which reads as a peptide “comprising” an amino acid sequence of SEQ ID NO:2 or 3.

In response, applicants indicate Montal *et al.* disclose the peptides obtained from the C-terminal domains of SNAP-25 inhibit the secretion of neurotransmitters from synaptic vesicles, while applicant’s claimed peptide fragments are derived from N-terminal domain of SNAP-25 and inhibit neuronal exocytosis, where the peptides have less than 20 amino acids; and Montal *et al.* do not disclose the short peptides outside the substrate binding domain of SNAP or containing the cleavage regions by clostridium neurotoxins could act as inhibitor of exocytosis (pages 8-10 of the response).

Applicant’s response has been considered, however, the argument is not found persuasive because Montal *et al.* disclose the amino acid sequence of SNAP-25 which comprises the amino acid sequence of SEQ ID NO:2 or 3, and meets the criteria of claims 1 and 2. Applicant indicates the claimed peptides are derived from N-terminal domain of SNAP-25, inhibit neuronal

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exocytosis, and have less than 20 amino acids, however, these limitations are not cited in the claims, thus the SNAP-25 protein I is not different from the claimed peptides.

14. Claims 1, 2, 11 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Fasshauer *et al.* (Biochemistry 37, 10354-10362 (published on Web on July 3, 1998)).

Fasshauer *et al.* teach the purified ternary complex of synaptobrevin, SNAP and syntaxin was subjected to limited proteolysis using chymotrypsin, trypsin and proteinase K, and the analysis of the fragments from SNAP-25 indicates the resulting N-and C-terminal fragments generated by the two proteases (trypsin and proteinase K) remained in the SDS-resistant core complex, and N-terminal fragments are residues 2-83, which contains SEQ ID NO:2 or 3 (page 10357; Fig. 2; claims 1 and 2), and C-terminal fragments generated by trypsin are from residues 120 or 125 to the end of C-terminal of SNAP-25, which contain SEQ ID NO:5 or 6 (page 10357, Fig. 2; claims 11 and 12). Since the patentability of a product claim is determined by the product, not by the process (see MPEP 2113), the term “synthetic” does not have weight in the claimed peptide, thus the reference anticipates the claimed invention.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

A handwritten signature in black ink, appearing to be 'Chih-Min' followed by a long horizontal stroke.

CMK
December 29, 2004